DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 2, 2016

Exactech, Incorporated
Mr. Graham L. Cuthbert
Regulatory Affairs Specialist II
2320 N. W. 66th Court
Gainesville, Florida 32653

Re: K092900
Trade/Device Name: Exactech® Equinoxe® Platform Fracture Stem
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWT, KWS
Dated: December 22, 2009
Received: December 23, 2009

Dear Mr. Cuthbert:

This letter corrects our substantially equivalent letter of January 7, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092900

Exactech® Equinoxe® Platform Fracture Stem
Traditional 510(k)

510(k) Number: K092900

Device Name: Exactech® Equinoxe® Platform Fracture Stem

INDICATIONS FOR USE:
The Equinoxe Shoulder System is indicated to relieve pain and restore function in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemi- arthroplasty is determined by the surgeon to be the preferred method of treatment.

Clinical indications for the PRIMARY (P), LONG/REVISION (L), and FRACTURE (F) humeral components are as follows:

P	L	F	Indications
√	√		Rheumatoid arthritis, osteoarthritis, osteonecrosis or post-traumatic degenerative problems
√	√		Congenital abnormalities in the skeletally mature
√			Primary and secondary necrosis of the humeral head.
√		√	Humeral head fracture with displacement of the tuberosities
√	√		Pathologies where arthodesis or resectional arthroplasty of the humeral head are not acceptable
√	√		Revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved)
		√	Displaced three-part and four-part upper humeral fractures
	√		Spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases)
	√		Revision of failed previous reconstructions when distal anchorage is required
√	√		To restore mobility from previous procedures (e.g. previous fusion)

The Equinoxe Reverse Shoulder System is indicated to relieve pain and restore function in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

The Equinoxe Platform Fracture Stem is indicated to relieve pain and restore function in skeletally mature individuals with acute fracture of the proximal humerus and displacement of the tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty).

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Exactech® Equinoxe® Platform Fracture Stem
Traditional 510(k)

Prescription Use ___X___ **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXor

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092900

K092900

Exactech® Equinoxe® Platform Fracture Stem
Traditional 510(k)

JAN - 7 2010

Company:	Exactech, Inc
Date:	January 5, 2010
Contact Person:	Graham L. Cuthbert, Regulatory Affairs Specialist II
Proprietary Name:	Exactech® Equinoxe® Platform Fracture Stem
Common Name:	Proximal Humerus Fracture Prosthesis
Classification Name:	Shoulder joint metal/polymer non-constrained cemented prosthesis (21 CFR 888.3650, Class II, Product Code KWT) Prosthesis, Shoulder, Semi-constrained, metal/polymer cemented (21 CFR 888.3660, Class II, Product Code KWS)

Legally Marketed Devices to Which Substantial Equivalence Is Claimed

- Equinoxe Fracture Stem (#K042021)
- Equinoxe Fracture Humeral Adapter Tray (#K073688)
- Zimmer Anatomical Shoulder Fracture System (#K062029)
- Biomet Comprehensive Shoulder Fracture System (#K023063)
- Biomet Comprehensive Reverse Shoulder (#K080642)
- Tornier Aequalis Shoulder Fracture System & Aequalis Shoulder System (#K060209)
- Tornier Aequalis Shoulder Reversed Adapter (#K071948)

Device Description

The Equinoxe Platform Fracture Stem is a humeral stem for use in acute fracture of the proximal humerus. The stem is designed to function with the Equinoxe primary shoulder and reverse shoulder components. All components are supplied sterile.

Indications for Use

The Equinoxe Shoulder System is indicated to relieve pain and restore function in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemi- arthroplasty is determined by the surgeon to be the preferred method of treatment.

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Traditional 510(k)

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√	√		Revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved)
		√	Displaced three-part and four-part upper humeral fractures
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The Equinoxe Platform Fracture Stem is indicated to relieve pain and restore function in skeletally mature individuals with acute fracture of the proximal humerus and displacement of the tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty).

Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use.** Equinoxe Platform Fracture Stem and predicate devices are intended for use in repairing acute fractures of the proximal humerus and have similar indications for use statements.
- **Materials.** Equinoxe Platform Fracture Stem and predicate devices are composed of comparable materials conforming to recognized industry standards for permanent implants.
- **Dimensions.** Equinoxe Platform Fracture Stem and predicate device components are available in equivalent size ranges.

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- **Sterilization processes.** Equinoxe Platform Fracture Stem and predicate devices are sterilized using equivalent sterilization processes conforming to recognized industry standards.
- **Performance specifications.** Equinoxe Platform Fracture Stem and predicate devices conform to recognized performance standards for total shoulder joint replacement devices.

Substantial Equivalence Conclusion

Mechanical tests, engineering analyses, and simulated surgical (sawbones and cadaver) implantations were performed with results demonstrating that the Equinoxe Platform Fracture Stem is substantially equivalent to the identified predicate devices.